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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,625	11/02/2001	Gerardo Castillo	PROTEO.P18	5292

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/053,625	<b>Applicant(s)</b> CASTILLO ET AL.	
	<b>Examiner</b> Christopher R. Tate	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18,31,33-39 and 52-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 52 is/are allowed.
- 6) ☒ Claim(s) 31,33-39 and 53-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

The amendment filed June 24, 2004 is acknowledged and has been entered. Claims 18, 31, 33-39, and 52-60 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 102***

Claims 31, 33-39, and 53-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasegawa Co (JP 04145048) or by Hasegawa Co (JP 04145049), to name a few.

A pharmaceutical agent and/or pharmaceutical composition comprising fraction F (chlorogenic acid) is claimed.

Each of the cited references teach compositions for use within pharmaceuticals which comprising chlorogenic acid (which, as readily admitted by Applicants, reads upon fraction F - see, e.g., Example 13 on pages 45-47 of the instant specification) as the active ingredient therein (see DWPI Abstracts).

Accordingly, each of the cited references is deemed to anticipate the instant claims above.

Claims 31 and 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by the admitted state of the art, with evidence provided by the Sigma Chemical Co. catalog (1994 ed) and the Aldrich Chemical Co. catalog (1990-1991 ed).

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As readily admitted by Applicants, commercial chlorogenic acid such as sold by Sigma Chemical Co. or by Aldrich Chemical Co. effectively provide the instantly claimed/disclosed functional effect.

Accordingly, each of the cited references is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 33-39, and 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasegawa Co (JP 04145048) or by Hasegawa Co (JP 04145049) and the Sigma Chemical Co. catalog (1994 ed) or the Aldrich Chemical Co. catalog (1990-1991 ed).

Each of the JP references teach compositions for use within pharmaceuticals comprising chlorogenic acid (which, as readily admitted by Applicants, reads upon fraction F - see, e.g., Example 13 on pages 45-47 of the instant specification) as the active ingredient therein (see DWPI Abstracts).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare pharmaceutical compositions comprising chlorogenic acid as an active ingredient therein based upon the beneficial teachings provided by each of the JP reference; as well as to substitute and/or incorporate a readily available commercial source of

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purified chlorogenic acid such as that manufactured and sold from Sigma Chem. Co and/or Aldrich Chemical Co. within such a pharmaceutical composition given the beneficial teachings provided by the Hasegawa references with respect to the advantageous use of chlorogenic acid as an active ingredient within pharmaceuticals.

Thus, the invention as a whole is clearly *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

With respect to the art rejections above, it is noted that the references do not teach that the reference compositions can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference compositions (see, e.g., MPEP 2112).

### ***Double Patenting***

Claims 31, 33-39, and new claims 53-59 are/remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,264,994.

Claims 31, 33-39, and new claims 53-59 are/remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/938,987; and over claims 9-15 of copending Application No. 10/099,637.

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In the response of June 24, 2004, Applicant did not argue the above obviousness-type double patenting rejections. On page 10 of the June 24, 2004 response "Applicant agrees to submit an appropriate form of terminal disclaimer to obviate these rejections".

However, until such time as an appropriate form of terminal disclaimer is submitted the above double patenting rejections stand.

To hasten prosecution, it is suggested that the product claims (claims 31, 33-39, and 53-60) be canceled in response to this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Conclusion**

Claims 18 and 52 are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate  
Primary Examiner  
Art Unit 1654